



## HIV Pre-Exposure Prophylaxis (PrEP)

### What is HIV PrEP?

- PrEP is a once-daily pill that can reduce a person's HIV risk by over **90%** when taken daily.
- PrEP is recommended by the Centers for Disease Control and Prevention (CDC) since 2014 and was approved in 2012 by the FDA as one strategy for HIV risk reduction among adults and adolescents (>35 kg) at substantial risk for HIV.
- PrEP is a combination of two anti-retroviral agents (TRUVADA; tenofovir disoproxil fumarate/300mg and emtricitabine/200mg) which have been used, at higher dosages and in combination with other drugs, for the treatment of active HIV infection for over a decade.
- PrEP is highly safe and well-tolerated. About 10% of PrEP users experience a "start-up" syndrome characterized by nausea and fatigue which typically resolves in 3-4 weeks. There is a risk of decreased renal function or bone mineral density, so people on PrEP are periodically monitored for serum creatinine levels and a baseline bone density scan might be considered for patients with a history of, or at risk for osteoporosis.



### Is PrEP part of the U.S. National HIV-AIDS Strategy to reduce HIV infections?

Yes. Objective 1.B.3 is to expand access to PrEP; objective 2.A.1 seeks to ensure health care coverage for PrEP; objective 3.A.1 seeks to expand services such as PrEP within communities at high risk for HIV, including men who have sex with men; and Indicator 12 (developmental) is to increase PrEP use among adults by 500% by 2020.

### What is DoD policy regarding PrEP?

- DHA IPM 18-020: Guidance for the Provision of Human Immunodeficiency Virus (HIV) Pre-Exposure Prophylaxis (PrEP) for Persons at High Risk of Acquiring HIV Infection requires all military medical facilities to provide a pathway to HIV PrEP for all DoD healthcare beneficiaries.
- PrEP use does not affect accession eligibility, reenlistment eligibility or readiness status.
- The US Navy Aeromedical Reference and Waiver Guide – Misc Conditions; 17.4.1 requires observation of no significant adverse effects due to Truvada during a 14-day grounding period.
- PrEP is available through the Tricare pharmacy formulary.
- PrEP is presently being used in many DoD medical facilities.

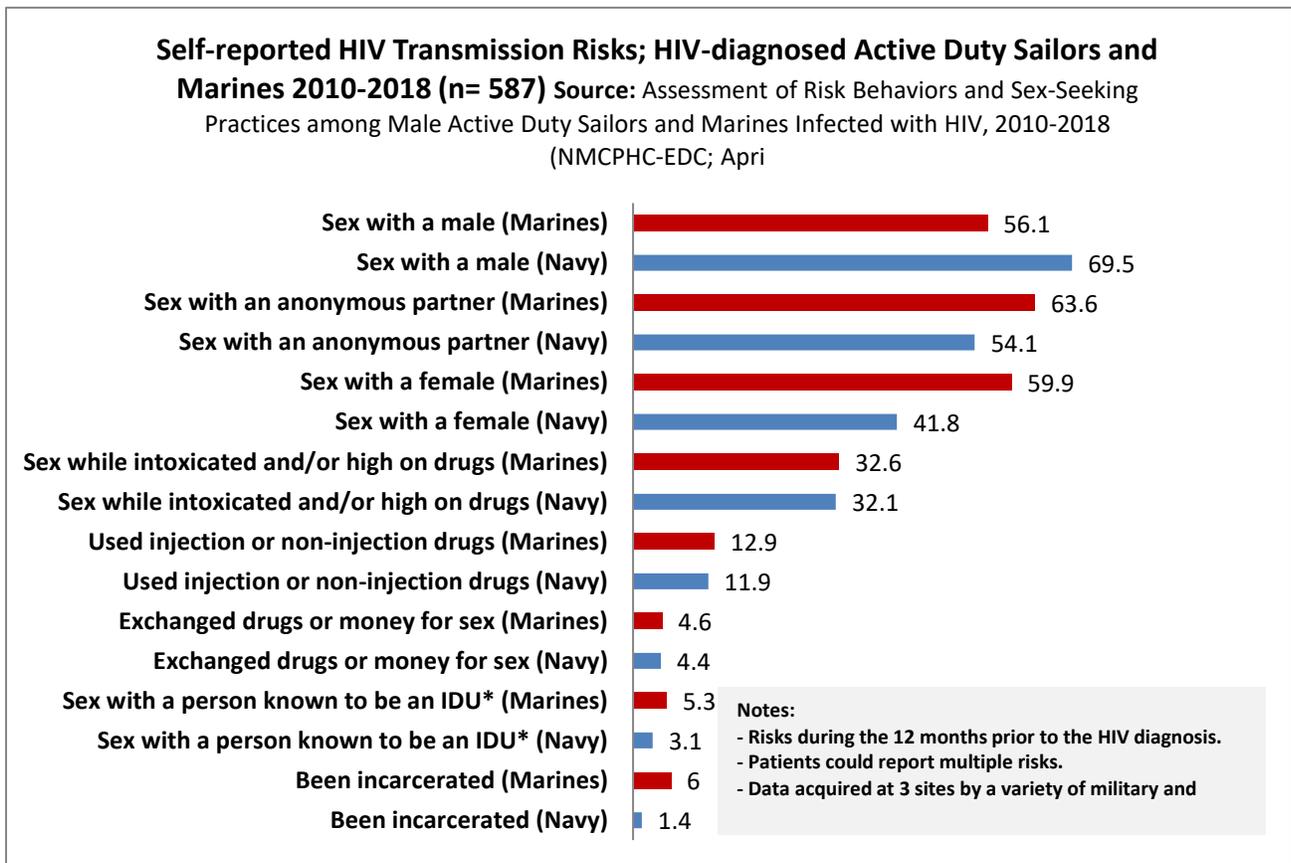
### Might PrEP disinhibit condom use?

Some, though not all, individuals using PrEP may consider that PrEP reduces the risk of HIV transmission to such an extent that they are willing to have condom-less sex when taking PrEP. Among PrEP-eligible people who presently use condoms on a consistent basis, such disinhibition to condom use could increase their exposure to other sexually transmitted infections (STIs). Therefore, people using PrEP should be counseled that condom use, along with PrEP, can increase both HIV prevention and the prevention of other STIs and can decrease the risk of an unwanted pregnancy. Beyond HIV risk reduction, an additional benefit PrEP is that PrEP patients are counseled about risk-reduction every 3 months and are screened for bacterial STIs every six months (at the time of their refill appointments). These are people, whose present circumstances place them at high risk, who may have otherwise received no STI screening or risk-reduction counseling.



**Who might benefit from PrEP?**

- PrEP is recommended for HIV-negative adults at very high risk for getting HIV from sex or injection drug use. PrEP was also approved by the FDA for adolescents >35kg in May 2018.
- PrEP should be considered for people who are HIV-negative and are:
  - In an ongoing sexual relationship with an HIV-positive partner.
  - Men and transgender women who currently have condomless receptive anal sex with men outside a mutually monogamous relationship with a partner who recently tested HIV-negative.
  - Men and transgender women who have sex with men and have been diagnosed with a rectal sexually transmitted infection in the past 6 months.
  - Heterosexual men or women who do not regularly use condoms during sex with partners of unknown HIV status who are at substantial risk of HIV infection (for example, people who inject drugs or women who have bisexual male partners).
  - People who have injected drugs in the past 6 months and have shared needles or works or have been in drug treatment in the past 6 months.
  - HIV negative women with an HIV-positive partner who are considering getting pregnant may consider the risks and benefits of PrEP as one strategy to reduce the risk of HIV infection for herself and her baby while trying to get pregnant, during pregnancy, or while breastfeeding.
- In the U.S., recent HIV rates have been highest among men who have sex with men. Although men who have sex with men make up only about 2% of the population of the U.S., they account for about 64% of all new HIV infections. The CDC estimates that 1 of 4 men who have sex with men could benefit from HIV PrEP. Young, black men who have sex with men are diagnosed with HIV at rates much higher than white or Hispanic men who have sex with men.





- Among active duty Sailors and Marines,
  - About 98% of all HIV infections occur among men.
  - Risks reported during the 12 months preceding their HIV diagnosis among male Sailors and Marines:
    - Over 6 of 10 report sex with a man.
    - About half report sex with an anonymous partner and/or sex with a female partner.
    - About one-third report sex while intoxicated or high.
  - HIV seroconversion rates highest among black male enlisted Sailors and Marines.

### **How might a healthcare provider begin a conversation about sexual risk and PrEP with a patient?**

Some helpful tools:

- NMCPHC Video: *Male Patient Sexual Risk Assessment*. Available on the SHARP Toolbox DVD Also available on [SWANK](#) (for DoD Medical Treatment Facilities only; Course Number 001).
- Sexual Risk Assessment - Brief Counseling Guide (for routine primary care patients (NMCPHC)).

### **What should the healthcare provider and PrEP-interested person discuss?**

For eligible and interested patients, the clinician should:

- Consider the patient's motivation and capacity to adhere to a daily dosing schedule.
- Ensure the patient is HIV-negative:
  - Test for HIV. (Rapid test is acceptable; Recommend a negative HIV test within the 7 days preceding PrEP start date).
  - Screen for recent symptoms of acute HIV infection (fever, fatigue, myalgia/arthritis, rash, headache, pharyngitis, cervical adenopathy, night sweats, diarrhea). If symptomatic, obtain an 4<sup>th</sup> generation HIV antibody/antigen assay and a negative nucleic acid amplification test (NAAT) or viral load test at that visit.
- Screen for vaginal/urethral, pharyngeal and rectal gonorrhea and chlamydia; screen for syphilis.
- Screen for serum creatinine (contraindicated if CrCl<60 ml/min).
- Screen for pregnancy, Hepatitis B Surface Antigen and Hepatitis C Antibody (not contraindications but follow-up if positive).
- Discuss and provide a medication fact sheet which includes dosing information, storage, missed doses and side effects. See the CDC PrEP Clinical Providers Supplement.
- Prescribe a 30-day supply of PrEP (only after documentation of negative HIV status) and schedule follow-up visit to assess and retest for HIV.
- Obtain repeat serum creatinine at 30 days to ensure renal function remains stable prior to prescribing another 60 days to get the patient to their next 3 month in-person visit.
- Thereafter, visits, counseling and HIV testing occur every 3 months and 90 day supplies of Truvada are provided.
- Semi-annually, the PrEP user is tested for STIs and kidney function.
- Annually, hepatitis C antibody testing is required.

### **What should a PrEP user know?** PrEP counseling should include these messages:

- Daily dosing is recommended to achieve maximum protection from HIV. Intermittent or episodic dosing is not recommended. (Identify and address barriers to daily medication adherence).
- PrEP does not afford protection the day the patient begins taking it. PrEP reaches protective levels in rectal tissues in approximately 7 days and in blood and cervicovaginal tissues at approximately 20 days.
- HIV prevention can be increased when PrEP is combined with other strategies such as condom use. (An interactive, on-line risk-estimator tool that can be reviewed with the patient is available at: <https://www.cdc.gov/hivrisk/>)



- HIV PrEP provides no protection for STIs other than HIV and no protection from pregnancy. Although many common STIs are curable, and STI screening will be done for the patient every 6 months, some STIs, such as genital herpes and genital warts, are treatable but not necessarily curable.
- People with active HIV infection should not use PrEP because they could develop resistance to the drugs in Truvada, which would compromise future options treatment for active HIV infection.
- For patients with current Hepatitis B Virus (HBV) infection: Truvada is active against HBV as well as HIV. When people with HBV stop taking PrEP – or if HBV develops resistance to it – the virus may reactivate, potentially leading to flares of increased liver inflammation and worsening liver injury. Therefore, patients with current HBV infection should be counseled against stopping PrEP until first consulting the clinician.

### **How long do people continue using PrEP?**

A person can remain on PrEP until their circumstances change and they or their doctor feel they no longer need it. The clinician should initiate a conversation about PrEP continuance at least every 12 months.

**What about periods of deployment?** There is no express prohibition of HIV PrEP use among shipboard members or deployed members. If the member expresses an intention to engage in high-HIV risk while deployed, then continuation of PrEP during deployment should be explored and, if possible, accommodated. The main challenges are to secure quarterly refills, counseling and quarterly 4th generation HIV Ag/Ab tests while underway. If, in the opinion of Ship Medical or the operational theater medical authority, it will not be possible to fully comply with the clinical practice guidelines, PrEP should be discontinued during that time and the member should be counseled about other HIV prevention strategies and the start-up delay when they restart PrEP after the deployment.

**How should I code PrEP in the electronic health record?** One suggestion is to use ICD 10 code: Z20.2 – contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission

**Where can I get more information? Visit NMCPHC-SHARP HIV Prevention page at:**

<https://www.med.navy.mil/sites/nmcphc/health-promotion/reproductive-sexual-health/Pages/hiv-preventionresources.aspx>